REMARKS

Claims 8, 10, 57, 58 and 61-67 were pending in the application. Claims 8, 57, 58, 61 and 62 have been amended. Accordingly, after the amendments presented herein have been entered, claims 8, 10, 57, 58, and 61-67 will remain pending. For the Examiner's convenience, these claims are presented herein in Appendix A.

Support for the amendments to the claims can be found throughout the specification and in the claims as originally filed.

No new matter has been added. Any cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to expedite the prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Information Disclosure Statement

The Examiner has objected to references D8 to E12 of the information disclosure statement filed on January 20, 2001 as not being in the correct format.

Applicants submit herewith a substitute Form PTO-1449 presenting references D8-E12 in the correct format. Applicants respectfully submit that the GenBank reports cited in D8-E1 were generated by the Assignee and have been provided to assist the Examiner in understanding the relevance of the GenBank records cited in the Form PTO-1449. It is from these GenBank search reports that Applicants became aware of many of the GenBank references (E2-E12) cited in the Form PTO-1449. Each GenBank search report includes the alignments of the 9qm or 9ql molecules of the invention with various hits from the GenBank EST, non-redundant nucleic acid or non-redundant protein database.

Applicants suggest that the above information should be adequate to assist the Examiner in considering these references. Therefore, Applicants respectfully request that the Examiner initial the Form PTO-1449 submitted on January 20, 2001, and return a copy of the initialed form to Applicants to signify that the aforementioned references have been considered and made of record.

Acknowledgement of the Withdrawal of Certain Rejections and the Indication of Certain Claims as Allowable

Applicants gratefully acknowledge the withdrawal of the previous rejections under 35 U.S.C.§ 112, first and second paragraph, as well as the withdrawal of the previous rejection under 35 U.S.C.§ 102(e).

Applicants further gratefully acknowledge the indication of claims 63 and 64 as being allowable.

Rejection of Claims 8, 10, 57, 58 61, 62, 66 and 67 Under 35 U.S.C.§ 112, First Paragraph

The Examiner has rejected claims 8, 10, 57, 58, 61, 62, 66 and 67 under 35 U.S.C. §112, first paragraph because, according to the Examiner, "the specification, while being enabling for an amino acid of SEQ ID NO: 20, does not reasonably provide enablement for an amino acid sequence which is 90%, 95% identical to SEQ ID NO: 20, or an amino acid sequence which comprises at least 15 contiguous amino acids of SEQ ID NO: 20 or a polypeptide comprising 15 amino acids of SEQ ID NO: 20, comprising a calcium binding domain." Specifically, the Examiner is of the opinion that

> Applicant argues that the claims include a functional limitation wherein the polypeptide is capable of interacting with a potassium channel. However, claims 8 and 10 do not include a functional limitation for the claimed polypeptides. Additionally, newly presented claims 66 and 67 also do not contain a functional limitation for the claimed polypeptides, they are only drawn to polypeptides that comprise a calcium binding domain. Since detailed information regarding the structural and functional requirements of the peptides are lacking, it is unpredictable as to which encoding variations, if any, meet the limitations of the claims. Furthermore, since the claims encompass an amino acid sequence which is 90%, 95% identical to SEQ ID NO: 20, or an amino acid sequence which comprises at least 15 contiguous amino acids of SEQ ED NO: 20 or a polypeptide comprising 15 amino acids of SEQ ED NO: 20, comprising a calcium binding domain, while the claims do not recite a functional limitation for the encompassed amino acid sequences, there is not sufficient direction as to how to use the encompassed polypeptides which do not interact with a potassium channel. Since no functional language is associated with claims 8, 10 and 66-67, one of ordinary skill in the art would not know how to use these defined sequences except in further characterization of the sequences themselves.

> Applicant argues that with regards to claims 57-58 and 61-62, the claims are similar to Example 14 of the Revised Interim Written Description Guidelines, wherein protein variants that are 95% identical to a sequence and that catalyze a reaction meet the written description requirement. In the instant case, claims 57-58 and 61-62 are drawn to polypeptides that are capable of interacting with a potassium channel. However, this is not a specific functional limitation for the claimed polypeptides since the term "interacting" is indefinite (see *infra*). It is not clear whether the polypeptides encompassed by the claim must actually bind and modulate the potassium channel, or are associated with a potassium channel in some other way, or simply "interacts" with the potassium channel simply by being in the same cell. ***Changing the functional limitation to make it clear that the encompassed polypeptides can bind and modulate the potassium channel activity would obviate this rejection. (Emphasis Added)***

While in no way conceding the validity of the Examiner's rejection and solely in the interest of expediting prosecution, Applicants have amended the claims thereby rendering the foregoing rejection moot. Specifically, Applicants have amended the claims to be directed to polypeptides that ***bind to and/or modulate a potassium channel activity***, as suggested by the Examiner. In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

The Examiner has further rejected claims 8, 10, 57, 58, 61, 62, 66 and 67 under 35 U.S.C. §112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Specifically, the Examiner is of the opinion that

> [t]hese are genus claims. The claims are drawn to amino acid sequences which are 90%, 95% identical to SEQ ID NO: 20, or an amino acid sequence which comprises at least 15 contiguous amino acids of SEQ ED NO: 20 or a polypeptide comprising 15 amino acids of SEQ ED NO: 20, comprising a calcium binding domain. The specification and claim do not indicate what distinguishing attributes shared by the members of the genus. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the encoded SEQ ID NO: 20. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted.
>
> The Examiner further asserts that

> Applicant argues that with regards to claims 57-58 and 61-62, the claims are similar to Example 14 of the Revised Interim Written Description Guidelines, wherein protein variants that are 95% identical to a sequence and that catalyze a reaction meet the written description requirement. In the instant case, claims 57-58 and 61-62 are drawn to polypeptides that are capable of interacting with a potassium channel. However, as set forth above, claims 57-58 and 61-62 are drawn to polypeptides that are capable of interacting with a potassium channel. However, this is not a specific functional limitation for the claimed polypeptides since the term "interacting" is indefinite (see *infra*). It is not clear whether the polypeptides encompassed by the claim must actually bind and modulate the potassium channel, or are associated with a potassium channel in some other way, or simply "interacts" with the potassium channel simply by being in the same cell. ***Changing the functional limitation to make it clear that the encompassed polypeptides can bind and modulate the potassium channel activity would obviate this rejection. (Emphasis Added)***

While in no way conceding the validity of the Examiner's rejection and solely in the interest of expediting prosecution, Applicants have amended the claims thereby rendering the foregoing rejection moot. Specifically, Applicants have amended the claims to be directed to polypeptides that ***bind to and/or modulate a potassium channel activity***, as suggested by the Examiner. In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

Rejection of Claim 65 Under 35 U.S.C.§ 112, First Paragraph

The Examiner has rejected claim 65 under 35 U.S.C.§ 112, first paragraph "as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Specifically, the Examiner states that

> Applicants have provided the deposit number for plasmid 98991 and 98993, but the specification is not fully compliant with all of the provisions for maintenance and availability of the deposited material. If a deposit is made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g. see 961 OG 21, 1977), and Applicants, their assignee or their agent needs to provide a declaration.

As required under 37 C.F.R. §1.804(b), Applicants state herein that the plasmids containing the full length nucleotide sequence encoding human 9qm and 9ql and deposited with the ATCC as Accession Numbers 98993 and 98991, respectively, are plasmids specifically identified in U.S. Serial No. 09/670,756. These deposits were made under the conditions of the

Budapest Treaty and comply with the preservation and public disclosure requirements of M.P.E.P. § 608.01 (p) (C). In addition, Applicants state herein that the deposits will irrevocably and without restriction or condition be released to the public upon issuance of a patent.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Rejection of Claims 57, 58, 61 and 62 Under 35 U.S.C.§ 112, Second Paragraph

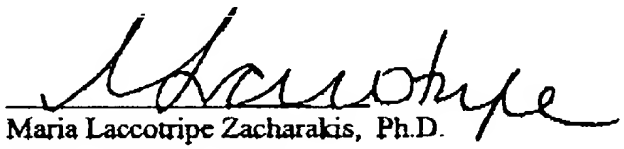
The Examiner has rejected claims 57, 58, 61 and 62 under 35 U.S.C.§ 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Specifically, the Examiner is of the opinion that "[c]laims 57, 58, 61 and 62 are vague and indefinite in the recitation of the term 'interaction'."

Applicants respectfully submit that, in view of the amendments to claims 57, 58, 61 and 62, this rejection has been rendered moot. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

SUMMARY

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

Respectfully submitted,



Maria Laccotripe Zacharakis, Ph.D.
Attorney for Applicants
Limited Recognition Under 37 C.F.R. §10.9(b)

LAHIVE & COCKFIELD, LLP
28 State Street
Boston, MA 02109
Tel. (617) 227-7400

Dated: September 2, 2003

APPENDIX A

8. **(Currently Amended)** An isolated polypeptide comprising at least 15 contiguous amino acids of the amino acid sequence of SEQ ID NO:20, wherein said polypeptide binds to and/or modulates a potassium channel.

10. **(Previously Presented)** The polypeptide of any one of claims 8, 57-58, or 61-67 further comprising heterologous amino acid sequences.

57. **(Currently Amended)** An isolated polypeptide which is encoded by a nucleic acid molecule comprising a nucleotide sequence which is at least 90% identical to a nucleic acid comprising the nucleotide sequence of SEQ ID NO:19, wherein said polypeptide binds to and/or modulates a potassium channel activity.

58. **(Currently Amended)** An isolated polypeptide which is encoded by a nucleic acid molecule comprising a nucleotide sequence which is at least 95% identical to a nucleic acid comprising the nucleotide sequence of SEQ ID NO:19, wherein said polypeptide binds to and/or modulates a potassium channel activity.

61. **(Currently Amended)** An isolated polypeptide comprising an amino acid sequence which is at least 90% identical to the amino acid sequence of SEQ ID NO:20, wherein said polypeptide binds to and/or modulates a potassium channel activity.

62. **(Currently Amended)** An isolated polypeptide comprising an amino acid sequence which is at least 95% identical to the amino acid sequence of SEQ ID NO:20, wherein said polypeptide binds to and/or modulates a potassium channel activity.

63. **(Previously Presented)** An isolated polypeptide comprising the amino acid sequence of SEQ ID NO:20.

64. **(Previously Presented)** An isolated polypeptide consisting of the amino acid sequence of SEQ ID NO:20.

65. **(Previously Presented)** An isolated polypeptide encoded by the DNA insert of the plasmid deposited with ATCC as Accession Number 98991, or 98993.

66. **(Previously Presented)** The isolated polypeptide of claim 8, wherein said polypeptide comprises a calcium binding domain.

67. **(Previously Presented)** The isolated polypeptide of claim 66, wherein said calcium binding domain is selected from the group of amino acid residues consisting of

a) amino acid residues 126-154 of SEQ ID NO:20;

b) amino acid residues 162-190 of SEQ ID NO:20; and

c) amino acid residues 210-238 of SEQ ID NO:20.